

REMARKS

Status of the claims:

With the above amendments, claims 1-8 have been canceled, claims 16-24 have been added, and claims 9-15 have been withdrawn from a prior restriction requirement. Thus, claims 9-24 are pending with claims 16-24 ready for further action on the merits. No new matter has been added by way of the above amendments. Support for claim 16 can be found in original claim 1. Support for claims 17 and 21 can be found in original claim 4. Support for claims 18, 19 and 22 can be found in original claim 7. Support for claim 20 can be found in original claim 1 and at page 13, lines 14-17, page 16, lines 12-14, page 18, lines 7-9, page 22, lines 4-7 and page 23, line 26 to page 27, line 2. Support for new claim 23 can be found in original claim 5. Support for new claim 24 can be found in original claim 8. Reconsideration is respectfully requested in light of the following remarks.

Translation

The Examiner asserts that no translation of the priority document has been received. Applicants respectfully point out that no translation is necessary unless there is an intervening art reference.

Rejections under 35 USC §112, second paragraph

Claims 1-8 are rejected under 35 USC §112, second paragraph as being indefinite. The Examiner asserts that the term "gene" is indefinite and has suggested replacing it with the term "polynucleotide". Applicants have amended the claims so that "gene" no longer appears in any of the examined claims. Accordingly, Applicants believe that the rejection has been obviated. Withdrawal of the rejection is warranted and respectfully requested.

The Examiner asserts that claim 1 should be amended to recite that the protein constituting a virus particle and the desired protein is fused. Applicants have canceled claim 1 so the rejection is moot with respect to that claim. With respect to the new claims, Applicants have indicated in both the preamble and in the body of the claim that a fusion protein is made. Accordingly, Applicants believe that the rejection has been obviated. Withdrawal of the rejection is warranted and respectfully requested.

The Examiner has rejected claim 4 for reciting "downstream". Applicants believe that the Examiner meant claim 6 as the word "downstream" does not appear in claim 4. Nevertheless, the rejection is moot as both claims 4 and 6 have been canceled. Claims 16 and 20 recite "wherein said first

polynucleotide is to a 5' side of said polynucleotide encoding said desired protein", which is unambiguous. Accordingly, Applicants believe that the rejection has been obviated. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §112, first paragraph

Claims 1-8 are rejected under 35 USC §112, first paragraph as allegedly lacking complete enablement. The Examiner asserts that the claims are enabled for a medium to low weight molecular size protein that can be fit into the viral gene. Accordingly, Applicants have presented claims that contain these elements in the claims.

Moreover, Applicants submit that the instant claims can be made and used without undue experimentation. Withdrawal of the rejection is warranted and respectfully requested.

Claims 1-8 are also rejected under 35 USC §112, first paragraph as allegedly lacking description. Applicants have canceled claims 1-8 so the rejection is moot with respect to those claims. Moreover, Applicants assert that full possession of the claimed invention was had at the time of filing the invention. The Examiner asserts that there is no written description for the deletion, addition, insertion and substitution of an amino acid residue. Applicants respectfully

point out that there is no language in any of the claims suggesting that this element is present. Accordingly, Applicants believe that the rejection is inapposite. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §102

Claims 1-5 are rejected under 35 USC §102(b) as being anticipated by Mottershead et al. (BBRC, 238, pp. 717-722, (1997)), Boublik et al. (Biotechnology, 13, pp. 1079-1084, (1995)), and Grabherr et al. (Biotechniques, 22(4), pp. 730-737, (1997)). Claims 1-5 have been canceled so the rejection is moot with respect to those claims. Applicants submit that none of the cited references can anticipate the currently pending claims as none of the references disclose a gene encoding the desired protein that is downstream of a coat protein, as was claimed in original claim 6, which is now present in new independent claims 16 and 20.

Having the desired protein downstream of the gp64 protein provides the advantageous effects that are well described in the specification (i.e., the transmembrane protein can be expressed in its native form). This generates a protein that is in its natural or active form, that is not inactive, such as proteins that exist in inclusion bodies. Accordingly, the cited references cannot anticipate the instant claims because the

cited references simply fail to disclose the instantly claimed elements. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §103

Claims 7 and 8 have been rejected under 35 USC §103(a) as being unpatentable over any of Mottershead et al., Boublik et al., or Grabherr et al. Applicants respectfully point out that the Examiner did not reject claim 6. Thus, Applicants believe that the incorporation of the elements of claim 6 into new independent claim 16 has obviated all of the art rejections.

Applicants submit that none of the cited references can render obvious the currently pending claims as none of the references disclose a gene encoding the desired protein that is downstream of a coat protein, as was claimed in original claim 6. When the desired protein is downstream of the coat protein (and particularly, gp64) advantageous effects are found that are well described in the specification (i.e., the transmembrane protein can be expressed in its native form). This feature and the effects thereof are neither disclosed nor suggested in any of the cited references.

Accordingly, Applicants assert that the Examiner has failed to make out a *prima facie* case of obviousness with regard to the 35 USC §103(a) rejection over any of Mottershead et al., Boublik

et al., or Grabherr et al. Three criteria must be met to make out a *prima facie* case of obviousness.

- 1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- 2) There must be a reasonable expectation of success.
- 3) The prior art reference (or references when combined) must teach or suggest all the claim limitations.

See MPEP §2142 and *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

In particular, the Examiner has failed to meet the third element to make a *prima facie* obviousness rejection. Because none of the references disclose a gene encoding the desired protein that is downstream of the gp64 protein, none of the references can render *prima facie* obvious the instant invention.

Moreover, even if a *prima facie* case of obviousness were made, which Applicants will not concede, having the desired protein downstream of the coat protein (and particularly, pg64) generates a protein that is in its natural or active form, that is not inactive, such as proteins that exist in inclusion bodies. Accordingly, the instant invention possesses unexpectedly superior effects that could never be surmised by the teachings of the cited references. Thus, the rejection is

inapposite. Withdrawal of the rejection is warranted and respectfully requested.

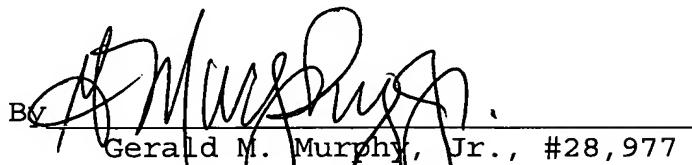
With the above remarks and amendments, it is believed that the claims, as they now stand, define patentable subject matter such that passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

If any questions remain regarding the above matters, please contact Applicant's representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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